

SIR:

Please amend the application filed on even date herewith prior to proceeding with its examination.

IN THE CLAIMS

1. (Original) A patch suitable for transdermal or local administration of at least one active principle comprising:

a) a matrix based on pressure sensitive adhesive silicone polymers containing:

a-1) said active principle in concentrations between 1 and 10% by weight on the total weight of said dry adhesive matrix,

a-2) said silicone polymers in quantities between 80 and 98% by weight on the total weight of said dry adhesive matrix,

a-3) at least one copolymer of cationic type of acrylic and/or methacrylic esters containing amino groups or salified ammonium groups in a concentration between 1 and 10% by weight on the total weight of said adhesive silicone polymers.

b) a support layer on which said adhesive matrix (a) is located,

c) a protective layer disposed on said adhesive matrix.

2. (Currently Amended) The patch as claimed in claim 1, [characterized in that] wherein the active principle is [chosen] selected from the [class] group consisting of drugs with urinary antispastic activity, drugs used for treating prostatic hypertrophy, steroidal hormones, steroidal anti-inflammatories, non-selective and selective beta blockers, calcium antagonists and benzodiazepines.

3. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing oxybutynin as] the active principle is oxybutynin.

4. (Currently Amended) The patch as claimed in claim 2, [characterized by]

wherein [containing an] the active principle is selected [chosen] from the group consisting of terazosin and finasteride.

5. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing an] the active principle is [chosen] selected from the group consisting of dehydroepiandrosterone and estradiol.

6. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] norethisterone [as] is the active principle.

7. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] ibuprofen [as] is the active principle.

8. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] piroxicam [as] is the active principle.

9. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] propranolol [as] is the active principle.

10. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing at] atenolol [as] is the active principle.

11. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] nifedipine [as] is the active principle.

12. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] clonazepam [as] is the active principle.

13. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] triazolam [as] is the active principle.

14. (Currently Amended) The patch as claimed in claim 2, [characterized by] wherein [containing] lorazepam [as] is the active principle.

15. (Currently Amended) The patch as claimed in [any one of claims 1-14]

claim 1, [characterized in that] wherein said adhesive silicone polymers are [chosen] selected from the group consisting of adhesive silicone polymer (III), adhesive silicone polymer (IV), and relative mixtures of said copolymers (III) and (IV).

16. (Currently Amended) The patch as claimed in claim 15, [characterized in that] wherein if [containing an] the active principle [containing] contains amino groups, adhesive silicone polymers (III) are used.

17. (Currently Amended) The patch as claimed in [any one of claims 15-16] claim 15, [characterized in that] wherein said silicone polymer (III) is at least one polymer [chosen] selected from the group consisting of (III-a), (III-b) and (III-c).

18. (Currently Amended) The patch as claimed in [any one of claims 15-16] claim 15, [characterized in that] wherein said silicone polymer (IV) is at least one polymer [chosen] selected from the group consisting of (IV-a), (IV-b) and (IV-c).

19. (Currently Amended) The patch as claimed in [any one of claims 1-18] claim 1, [characterized in that] wherein the copolymer (a-3) is [chosen] selected from the group consisting of:

i) copolymers of cationic type based on dialkylaminoalkylmethacrylate, and neutral alkylmethacrylate esters, where alkyl means a C₁-C₁₀ linear or branched alkyl residue, said copolymers having an average molecular weight between 100,000 and 500,000 and in which the ratio of repetitive dialkylaminoalkylmethacrylate/neutral ester units is between 2:1 and 1:2;

ii) copolymers of cationic type based on trialkylammoniumalkylmethacrylate, and neutral alkylmethacrylate esters, neutral alkylacrylate esters, where alkyl means a C₁-C₁₀ linear or branched alkyl residue, said copolymers having an average molecular weight between 100,000 and 500,000 and in which the alkylmethacrylate and

methacrylate/trialkylammoniumalkylmethacrylate ratio is between 40:1 and 20:1;

iii) mixtures of (i) and (ii).

20. (Currently Amended) The patch as claimed in claim 19, [characterized in that] wherein the copolymer is [chosen] selected from the group consisting of:

a-3-1) poly-(butylmethacrylate, (2-dimethylamino)-methacrylate, methylmethacrylate) in which the ratio of said 3 monomers is respectively 1:2:1, and is characterized by an average molecular weight of 150,000;

a-3-2) poly(ethylacrylate, methylmethacrylate, trimethylammoniummethylmethacrylate chloride) characterized by an average molecular weight of 150,000 and in which the ratio of said monomers is 1:2:0.2;

a-3-3) poly(ethylacrylate, methylmethacrylate, trimethylammoniummethylmethacrylate chloride) characterized by an average molecular weight of 150,000 and in which the ratio of said monomers is 1:2:0.1; and

a-3-4) mixtures of two or all the copolymers a-3-1), a-3-2), a-3-3).

21. (Currently Amended) The patch as claimed in claim 20, [characterized in that] wherein if the active principle is of basic type, said patch contains the component (a-3-3).

22. (Currently Amended) Patch as claimed in claim 20, [characterized in that] wherein if the active principle is of acid type, said patch contains the component (a-3-2).

23. (Currently Amended) A process for preparing the patch claimed in [any one of claims 1-22] claim 1, comprising the following stages:

α) adding the solution of the cationic polymer of acrylic and/or methacrylic esters containing amino groups or salified ammonium groups (a3) in an organic solvent to the solution of silicone PSA in the same organic solvent used for (a3),

β) adding the active principle to the mixture obtained in the preceding stage (α), and keeping the resultant mixture under stirring for 3 hours,

γ) spreading on the support (b) the mixture coming from the preceding stage (β), drying it and applying the protective sheet (c) with conventional machines.

24. (Currently Amended) The process as claimed in claim 23, [characterized by using] wherein solutions of silicone polymers are used in ethyl acetate, in which case the organic solvent of stage (α) is ethyl acetate.

25. (Currently Amended) The process as claimed in claim 24, [characterized in that] wherein said solutions of silicone polymers in ethyl acetate contain said polymer in concentrations of 60% by weight on the total weight of said solution.